TITLE PAGE

Title:

DEveloping a Complex Intervention for DEteriorating Patients using Theoretical Modelling (DECIDE study): study protocol

Running Head:

DECIDE study

Authors:

1st (corresponding author)	Duncan SMITH MSc MN RN e. Duncan.smith.1@city.ac.uk t. 07729749807 twitter username: @duncan281013 1. Clinical Doctoral Research Fellow and Lecturer (Advanced Practice) City, University of London School of Health Sciences Northampton Square London UK EC1V 0HB 2. Honorary Charge Nurse – Patient Emergency Response & Resuscitation Team (PERRT) University College London Hospitals NHS Foundation Trust Euston Road London UK NW1 2BU
2nd	Jill J FRANCIS PhD C. Psychol e. Jill.Francis.1@city.ac.uk 1. Professor of Health Services Research City, University of London School of Health Sciences Northampton Square London UK EC1V 0HB
LAST	Leanne M AITKEN PhD RN e. Leanne.Aitken.1@city.ac.uk

	1. Professor of Critical Care City, University of London School of Health Sciences Northampton Square London UK EC1V 0HB 2. School of Nursing and Midwifery Griffith University Nathan, QLD 4111 Australia

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ABSTRACT

Aim

To develop a theory-based complex intervention (targeting nursing staff), to enhance enablers and overcome barriers to enacting expected behaviour when monitoring patients and responding to abnormal vital signs that signal deterioration.

Design

A mixed method design including structured observations on hospital wards, field notes, brief, un-recorded interviews and semi-structured interviews to inform the development of an intervention to enhance practice.

Methods

Semi-structured interviews will be conducted with nursing staff using a topic guide informed by the Theoretical Domains Framework. Semi-structured interviews will be transcribed verbatim and coded deductively into the 14 Theoretical Domains Framework domains and then inductively into 'belief statements'. Priority domains will be identified and mapped to appropriate behaviour change techniques. Intervention content and mode of delivery (how behaviour change techniques are operationalised) will be developed using nominal groups, during which participants (clinicians) will rank behaviour change techniques /mode of delivery combinations according to acceptability and feasibility. Findings will be synthesised to develop an intervention manual.

Discussion

Despite being a priority for clinicians, researchers and policymakers for two decades, 'sub-optimal care' of the deteriorating ward patient persists. Existing interventions have been

largely educational (i.e., targeting assumed knowledge deficits) with limited evidence that they change staff behaviour. Staff behaviour when monitoring and responding to abnormal vital signs is likely influenced by a range of mediators that includes barriers and enablers.

Impact

Systematically applying theory and evidence-based methods, will result in the specification of an intervention which is more likely to result in behaviour change and can be tested empirically in future research.

KEYWORDS

behaviour, nursing, deteriorating patient, national early warning score (news), rapid response system, afferent limb failure, theoretical domains framework (tdf), focused observation

1. INTRODUCTION

Since a seminal paper that reported 'sub-optimal care' of deteriorating ward patients was published two decades ago (McQuillan et al., 1998) the recognition of and response to, a deteriorating patient in a hospital ward has been a priority of clinicians, academics and policy-makers. Patients who deteriorate are at risk of adverse outcomes such as cardiac arrest, unplanned intensive care admission and death (Calzavacca et al., 2010; Tirkkonen et al., 2013). These endpoints are frequently preceded by a period of physiological deterioration reflected by changes in vital signs, including: heart rate, respiratory rate, blood pressure, temperature, oximetry and level of consciousness (Goldhill & McNarry, 2004; Kause et al., 2004). A delay in the recognition of, or response to, these physiological antecedents increases the likelihood of a patient reaching an adverse outcome (Boniatti et al., 2014).

2. BACKGROUND

2.1 Rapid Response System

To facilitate a timely and clinically appropriate response to patient deterioration, healthcare organisations have implemented rapid response systems (RRS) in the UK, North America and Australasia (DeVita et al., 2006; Johnstone, Rattray, & Myers, 2007). Despite differences in the how these services have been operationalised, the characteristics are often similar. RRS frequently have an afferent and an efferent limb (DeVita et al., 2006) (see figure 1). In this context, 'limb' refers to a sequence of actions performed within a specified timeframe. Expected afferent limb behaviours include monitoring a patient's vital signs, recognising abnormality (which signals deterioration) and notifying a more senior or expert clinician (termed escalation), within a specified timeframe (DeVita et al., 2006; Lyons, Edelson, & Churpek, 2018). The mode of notification could include any combination of face-to-face

communication, telephone communication and use of technology, e.g., a hospital pager system (DeVita et al., 2006; Lyons, Edelson, & Churpek, 2018; Smith, 2010). These behaviours are typically enacted by nursing staff including registered nurses, pre-registration nursing students and health care assistants (Mackintosh, Humphrey, & Sandall, 2014; Smith & Aitken, 2016). The *efferent limb* of the RRS includes all actions that follow escalation performed by the responder/s (DeVita et al., 2006). Efferent limb behaviours include performing additional patient assessment, initiating treatment or stabilising interventions and facilitating a transfer of the patient to a higher-care setting for example a critical care unit (Bannard-Smith et al., 2016; DeVita et al., 2006; Lyons et al., 2018).

2.2 Track and trigger tools

To enhance the *afferent limb* of the RRS, 'track and trigger' tools have been widely implemented to facilitate identification of patients with deranged physiology requiring escalation. From the tools available, aggregate scoring track and trigger charts (also known as early warning scoring tools) appear to most reliably predict patients at greatest risk (Smith, Prytherch, Schmidt, & Featherstone, 2008). Specifically, the National Early Warning Scoring (NEWS) tool is advocated as the 'gold standard' in the UK context (Royal College of Physicians, 2017; Smith, Prytherch, Meredith, Schmidt, & Featherstone, 2013).

A key element of all track and trigger charts is to prompt nursing staff carrying out the clinical observations to increase the frequency of monitoring and to escalate. For NEWS, if the aggregate score generated from a complete set of vital signs (possible range: 0 - 20) equates to medium (score of 5 or 6 points) or high risk (exceeding 7), nurses are prompted to escalate (Royal College of Physicians, 2017). Despite escalation protocols or algorithms being explicitly linked to the track and trigger tool, there is evidence that nursing staff are failing to change their behaviour and increase the frequency of monitoring (Hands et al., 2013; Kolic, Crane,

McCartney, Perkins, & Taylor, 2015; Smith & Aitken, 2016) and escalate care, despite the relevant criteria being met (Odell, 2015; Shearer et al., 2012; Tirkkonen et al., 2013). This is described as 'afferent limb failure' (ALF) (Johnston, Arora, King, Stroman, & Darzi, 2014; Trinkle & Flabouris, 2011).

2.3 Afferent Limb Failure

Afferent limb failure poses (ALF) a significant threat to hospitalised patients. Despite this, the reasons for ALF remain poorly understood. Gaps in the existing body of knowledge were reported in a recently published integrative review of international studies related to nurses' recognition and response to deteriorating patients (Massey, Chaboyer, & Anderson, 2017). From the review, no studies were identified that explored how nurses monitor patients, how effective they are at monitoring, or how nurses use vital signs to recognise and respond to patient deterioration. Theorising and modelling the causal pathway to afferent limb failure using a behavioural focus will address this knowledge gap. It will also allow the development of specific interventions aimed at modifying behaviours that are proximal antecedents to ALF.

2.4 The Theoretical Domains Framework (TDF) of behaviour change

A published scoping review identified 83 different theories of behaviour and behaviour change (Davis, Campbell, Hildon, Hobbs, & Michie, 2014). Many of these theories are complex, making their use challenging for multi-disciplinary research teams and researchers without a background in health psychology (Michie et al., 2005). Furthermore, several of the constructs proposed in these theories are overlapping or related in meaning, making it difficult for researchers to identify which theory or construct is most appropriate for investigating a particular behavioural problem (Michie et al., 2005). In 2005, a group of cross-disciplinary experts used a consensus approach to synthesise 33 theories and 128 theoretical constructs to form an integrative framework (Michie et al., 2005) which became known as the Theoretical

Domains Framework (TDF). Following further refinement, a second iteration of the TDF comprising 14 domains (Figure 2) was validated (Cane, O'Connor, & Michie, 2012). The benefits of using the TDF to address behavioural problems include: its accessibility to researchers who lack expertise in health psychology or social sciences (Wilkinson et al., 2015); breadth of underpinning theory; and the broad coverage provided by the 14 domains that allows a wide range of barriers and enablers to behaviour change to be identified (Atkins et al., 2017; French, Green, O'Connor, McKenzie, & Francis, 2012; Wilkinson et al., 2015). Since its inception, a growing body of international research has emerged using the TDF to assess behavioural problems and develop behaviour change interventions targeting clinical staff (Craig et al., 2017; Roberts, Hooper, Lorencatto, Storr, & Spivey, 2017; Sargent, McCullough, Del Mar, & Lowe, 2017).

3. THE STUDY

3.1 Aim

The aim is to develop a theory-based complex intervention to enhance enablers and overcome barriers to performing expected afferent limb behaviours (e.g., monitoring patients and responding to abnormal vital signs).

Objectives

1. To compare behaviours observed on the hospital wards with the expected behaviours (as specified in local policy and national guidelines).
2. To identify where ALF is occurring in the sequence of observed behaviours and to offer theoretically formulated explanations for it.

3. Based on the theoretically formulated explanations, develop a complex intervention to target behaviours associated with ALF and assess the acceptability of the intervention to staff prior to feasibility testing (to be conducted as a separate study).

3.2 Design

Research will be conducted in three phases:

1. Structured observation and brief (un-recorded) interviews used to identify the causal pathway to ALF (addressing objective 1).
2. The Theoretical Domains Framework (TDF) will be used to investigate factors perceived by staff to influence their afferent limb behaviour (addressing objective 2).
3. The content (behaviour change techniques) and modes of delivery (e.g., face-to-face group training sessions, digital intervention) for the complex intervention will be informed by nominal groups with clinical stakeholders (addressing objective 3).

3.3 Recruitment & sampling

Phase 1

Recruitment will occur in a metropolitan teaching hospital in the UK. A minimum of 2 acute wards will be identified using local data. To elicit a wide range of enablers and barriers to afferent limb behaviour, contrasting wards will be recruited using criteria listed below:

Ward 1

- No reported adverse incidents involving patient harm associated with ALF within the past 12 months;
- High numbers of timely referrals to the local rapid response team.

Ward 2

- Will have reported 1 or more adverse incidents involving patient harm associated with ALF within the past 12 months;
- Low numbers of timely referrals to the local rapid response team.

This information is routinely presented at the hospital's deteriorating patient steering committee meeting. Permission has been granted to use these data to identify target wards. One hundred and eighty hours of fieldwork is proposed during the period of structured observation. This duration has been informed by published observational studies of similar focus and methods (Gillespie, Wallis, & Chaboyer, 2008; Mackintosh et al., 2014). Using a small sample of wards will allow the researcher to become immersed in each and ensure a 'thick description' of the setting and participant behaviour (Nannan Panday, Minderhoud, Alam, & Nanayakkara, 2017; Reeves, Kuper, & Hodges, 2008). This will also mitigate observer effects; increasing the likelihood that participants habituate to the researcher's presence (Pope, 2005). Senior nurses and ward managers for the selected wards will be issued with written information. If senior nurses do not give permission for their staff to be approached, the researcher will return to the local data to identify alternative wards.

A purposive sample (balance of clinical banding) of nursing staff will be recruited. Participants will be shadowed and observed, during a clinical shift, performing behaviours associated with the afferent limb, by one researcher (DS) with extensive clinical experience. There is evidence that frequency of monitoring and nursing staff compliance with escalation protocols decreases at night and during weekends (Hands et al., 2013; Kolic et al., 2015). Therefore, observation will be carried out during weekdays, weekends and overnight.

Phase 2:

A subset of staff (observed in phase 1) will be selected for a semi-structured interview. Some staff will have been observed enacting expected afferent limb behaviour; whilst others will have been observed not responding as expected (i.e., not seen to respond at all or seen to enact an unexpected behaviour). Data saturation will be determined as follows: 1.) an *initial analysis sample* of 10 interviews will be conducted with nursing staff; 2.) data from the *initial analysis sample* will be analysed and coded by two members of the research team; 3.) a *stopping criterion* of three will be used, meaning that saturation will be achieved when no new themes emerge from three subsequent consecutive interviews (Francis et al., 2010).

Phase 3:

Two nominal groups are planned, each including a purposive (balance of clinical discipline and banding) sample of 8-12 participants. This has been informed by published studies where nominal group techniques were used (Dening, Jones, & Sampson, 2013; Varga-Atkins, Bunyan, Fewtrell, & McIsaac, 2011; Williams, White, Klem, Wilson, & Bartholomew, 2006). Nursing staff from the 2 participating wards will be recruited for group 1 and members of the hospital's deteriorating patient steering committee (membership includes: medical staff, nurse managers, nurse educators and members of the local rapid response team) for group 2. These 2 separate groups will be selected to reduce the likelihood that an imbalance in power between participants has a negative impact on the group dynamic (Shaha, Wenzel, & Hill, 2011). Permission to electronically invite staff to participate will be sought from the ward managers and the committee Chair.

3.4 Materials

Structured observation guide

A documentary analysis of local deteriorating patient policy (Smith, Sekhon, Francis, & Aitken, 2019) will provide information about expected nursing staff behaviour, in relation to 'who should do what, to whom, when, where and how' (Michie, 2004). A structured observation guide will be developed (as described by Roller & Lavrakas, 2015) using these policy-specified behaviours. Policy-specified behaviours will be summarised as 'key moments' (signals to the researcher during fieldwork, to observe a behaviour and/or to carry out a brief interview) by one member of the research team (DS) with considerable experience in managing deteriorating patients. Key moments will be reviewed for appropriateness and clinical accuracy by a second member of the research team (LMA - a clinician with expertise in critical care research) and members of the hospital's rapid response team.

Field journal

A field journal will be maintained throughout the observation period to record observational data (Tracy, 2013) including:

- Contextual detail related to key moments (who, what, where, when, how)
- If, during the key moment, the expected behaviour was observed
- Whether an alternative behaviour was observed instead – 'unexpected behaviour'

Brief interviews with participants (following a key moment) will also be paraphrased in the field journal (Gillespie et al., 2008). Field notes will inform the questions asked during subsequent semi-structured interviews (particularly in relation to which specific afferent limb behaviours should be explored). As a registered nurse, with experience of managing deteriorating

patients, the researcher will need to maintain a high level self-awareness and situational awareness during data collection activities (attributes promoting 'reflexivity') (Tracy, 2013; Vindrola-Padros & Vindrola-Padros, 2018). To promote self-awareness and to allow transparency in later reporting of research outputs, the researcher's feelings, reactions and perceptions will also be recorded in the field journal as 'reflexive notes' (as advised by Roller & Lavrakas, 2015).

The observation guide and field journal will be piloted for 1 week and revised thereafter. During the pilot work, key moments, field notes and reflexive notes will be presented to 2 members of the research team (a professor of critical care and an implementation scientist), allowing data collection decisions to be challenged and defended and enabling revisions to the structure and content of the field journal.

Interview topic guide

An interview topic guide will be developed in collaboration with the research team (DS, LMA, JJF). The guide will be based on the 14 theoretical domains of the TDF (Atkins et al., 2017; Roberts et al., 2017; Sargent et al., 2017). Questions will be written broadly to explore the barriers and enablers to all behaviours recognised to be part of the afferent limb e.g., monitoring and recording vital signs, calculating NEWS, escalating to an appropriate clinician (Lyons et al., 2018). The interview guide will be piloted with nursing staff from a non-participating ward to ensure it is comprehensive and it makes clinical sense. Any revisions will be made prior to fieldwork. Observational and brief-interview data (from phase 1) will provide insight into which *specific* afferent limb behaviours are not consistently being enacted. Based on these observations, the topic guide will be revised iteratively to include additional, more focused questions targeting specific behaviours that need to be changed.

Nominal group materials

An information package will be developed for nominal group participants and issued prior to the nominal group meetings. The package will describe phases 1 and 2 of the research and will contain the list of behaviour change techniques (BCTs) synthesised from the mapping of priority TDF domains to the BCT taxonomy (Michie et al., 2013). The information package will be developed in collaboration with the research team (DS, LMA, MC) and reviewed by patient advisors. Documents have been developed (supplementary file 1) for individual participants to rank the acceptability (how well accepted the intervention component would be by recipients) and feasibility (how easily or conveniently the intervention component could be operationalised) of the selected BCT/mode of delivery combinations (Harvey & Holmes, 2012; Martins, Taylor, Morgan, & Fern, 2017; McMillan et al., 2014).

3.5 Data collection

Phase 1 – theorising the evidence-practice gap

Data collection strategies will include structured observation (on hospital wards), field notes and brief, un-recorded interviews with staff (conducted by DS). Using a structured observation guide, observation will focus on key moments when afferent limb behaviours should occur. These key moments will be identified from the literature and a documentary analysis of local deteriorating patient policy (Smith et al., 2019), making data-collection focused and deductive (Cruz & Higginbottom, 2013; Tracy, 2013).

Phase 2 – modelling the complex intervention

Semi-structured interviews will be conducted (by DS) with the same participants. Given the clinical context of the research, the timing of the interview will be negotiated with the

participant. Interviews will explore the factors that are perceived by staff to have influenced the observed behaviour. An interview topic guide will be developed using the Theoretical Domains Framework (TDF) (Cane et al., 2012; Francis, O'Connor, & Curran, 2012) and revised iteratively based on phase 1 field data. Interviews will be held in a private room, separate from the ward and digitally audio-recorded to enable transcription.

The priority domains for behaviour change will be identified through consensus discussion with the research team which comprises researchers with expertise in critical care nursing (LMA, DS) and implementation science (MC) using criteria reported in previously published work where the TDF was used (Atkins et al., 2017; Francis et al., 2010; Islam et al., 2012). Priority domains will be mapped to an appropriate taxonomy of behaviour change techniques (BCTs) (Michie et al., 2013) using a systematic method. BCTs are considered the 'active ingredients' of an intervention that bring about the change in behaviour (Michie, Atkins, & West, 2014). The mapping process will provide a preliminary list of possible techniques that may be used in combination as part of the complex intervention (Cane, Richardson, Johnston, Ladha, & Michie, 2015; French et al., 2012; Michie, Johnston, Francis, Hardeman, & Eccles, 2008). Example BCTs are provided in figure 3.

Phase 3 – deciding the content and mode of delivery

The behaviour change intervention literature distinguishes between the content of an intervention (i.e., the replicable components such as BCTs) and its mode of delivery (i.e., how those BCTs are delivered to intervention recipients) as some modes of delivering BCTs will be considered more acceptable in the local context (Michie et al., 2008). As such, the final content and mode of delivery will be informed by two nominal groups with clinical staff. The nominal groups will be facilitated by members of the research team (DS, LMA).

The structure and procedure for the nominal groups, informed by published studies where nominal groups were used (Dening et al., 2013; McMillan, King, & Tully, 2016; Varga-Atkins et al., 2011), will be as follows: 1.) before the group convenes, participants will be sent the information package; 2.) on arrival, the purpose, ground rules and structure of the group will be explained to participants; 3.) participants will be asked: *"Are there any other ways to deliver the BCTs from the list in my organisation, that were not included in the information package?"* and given time to individually respond to the question (and document their response on 'sticky' notes); 4.) all participants will be invited to openly share their responses (these will be displayed to the group) and to discuss, clarify and dispute the additional BCT/mode combinations; 5.) participants will work together to sort and group 'sticky' notes to generate agreed themes and priorities; 6.) participants will be asked to select the 5 BCT/mode combinations that are most acceptable and individually rank them from 1 (most acceptable) to 5; 7.) participants will be then asked to select the 5 BCT/mode combinations that are most feasible for local implementation and individually rank them from 1 (most feasible) to 5.

3.6 Data analysis

Phases 1 & 2

Analysis of field notes and transcripts of semi-structured interviews will be both deductive and inductive and will broadly follow Gale et al's (2013) 'framework method' using the following steps: 1.) transcripts will be reviewed for accuracy, revised where necessary and de-identified; 2.) initially, data will be deductively coded according to the TDF domains; 3.) utterances (sections of transcribed text reflecting responses from participants) within each domain will then be inductively sorted and grouped with other similar statements; 4.) a 'belief statement' will be synthesised to summarise the group of similar utterances (Islam et al., 2012; Roberts et al., 2017); 5.) to develop robust and defensible coding, belief statements will be reviewed

by an independent member of the research team (MC) to ensure that they adequately represent the utterances grouped beneath them. Any disagreements will be reconciled through consensus discussion (Roberts et al., 2017); 6.) for each belief statement, the frequency of utterances (including those where the domain is perceived to be a barrier to afferent limb behaviour and those where the domain is perceived to be an enabler to afferent limb behaviour) will be recorded. This will help identify domains that are potentially 'controversial' i.e., where there are conflicting beliefs expressed by one participant or between different participants. In this context, frequency will refer to the number of different participants who mention the theme (as opposed to the number of times mentioned). Any participant utterances where a domain is suggested to be particularly influential will also be highlighted i.e., if the participant uses emphatic language to report the influence on behaviour e.g., *"yes getting feedback is really, really important to me".* This information and the frequency of utterances, will be of particular importance when agreeing priority domains to target in subsequent phases of the research (Islam et al., 2012; Patey et al., 2012).

Phase 3

Through discussion, debate and review, the research team (DS, LMA, MC) will shortlist a final list of BCT/mode of delivery combinations. BCT/mode combinations that were ranked highly and/or frequently by the nominal group participants will be considered first by the research team during this process. Where there are significant discrepancies between the two groups, the research team will review the notes taken during the nominal groups (individually by participants and by the facilitator during the gathering of group ideas) to agree the final list of BCT/mode of delivery combinations. From the final list, an intervention manual will be developed by the research team and patient advisors which will include detail on how the intervention components will be operationalised during subsequent feasibility testing.

Ensuring rigour in data analysis

Ten percent of transcripts (from semi-structured interviews) will be randomly selected and coded independently by two clinical members of the research team (DS, LMA). A codebook will be developed to include key codes, definitions and exemplars (Gale, Heath, Cameron, Rashid, & Redwood, 2013; Tracy, 2013). Both researchers will meet to compare coding and calculate percentage agreement. The codebook will be reviewed iteratively, and the codes/definitions discussed and refined. Where consensus cannot be easily attained, an implementation scientist (MC) will be consulted. This process will be repeated until the calculated level of inter-coder agreement reaches 60% (Atkins et al., 2017; Landis & Koch, 1977) and both coders verbally agree on the codes/definitions. After inter-coder reliability has been demonstrated, all subsequent coding will be performed independently by one researcher (DS). Any additional uncertainties that arise during the independent coding process will be reconciled through consensus discussion with the research team (DS, LMA, MC).

4. ETHICAL CONSIDERATIONS

4.1 Procedure for consent

The researcher will contact ward managers, via email, to obtain permission to visit their wards and speak to staff. Once permission from ward managers has been given, the researcher will attend handover meetings and staff 'huddles' to provide verbal and written information to nursing staff on the goals and scope of the research. These interactions will take place over a period of 2-3 weeks, to ensure that all staff receive information about the study and are aware of how data will be collected and when these activities are planned. The researcher's email address will be shared with staff so that they can make contact individually and confidentially to request further information about the research. Consent will be managed using both 'opt-out' and 'opt-in' approaches.

Phase 1

'Opt-out' approaches have been cited as beneficial in obtaining more diverse and less biased sampling in studies considered to be low risk to participants (Junghans, Feder, Hemingway, Timmis, & Jones, 2005; Krousel-Wood, Muntner, Jannu, Hyre, & Breault, 2006; Vellinga, Cormican, Hanahoe, Bennett, & Murphy, 2011). Phase 1 of this study is considered low risk because 1.) participants are staff who can opt-out at any stage; 2.) participants will be observed carrying out normal activities i.e., activities considered part of their job role; 3.) no direct audio or video recordings of staff will be made during their normal work activities. In addition, as the observation focuses on specific staff behaviours, the opt-out approach in this context should enable the researcher to be time-efficient (several staff could be observed within one clinical shift); reduce the frequency of periods where no staff are enacting behaviours of interest (therefore reducing redundant collection); and ensure that the research runs to the proposed timeline. During phase 1, a range of strategies will be used to allow staff to opt out (e.g., staff can prospectively and privately complete an opt-out form and deposit it in a locked box in the staff room). For further details of opt out strategies and a copy of the opt out form, see supplementary file 2.

Phase 2

Following the observations, participants will be invited to take part in an individual interview. Contact with potential participants will be made by the researcher on an *ad-hoc* basis during observation. Only staff who volunteer and opt-in will be interviewed. Participants will be given written and verbal information about the interview (by the researcher) and will be asked to sign a consent form before they participate. Voluntariness of participation will be stressed on the consent form. Participants will also be asked for their consent to use direct quotations in outputs of this research.

Phase 3

Participants from phases 1 and 2 will be invited (via email) to attend a nominal group meeting in phase 3 of the study. These staff will be contacted initially at least 2 months prior to the date when the nominal groups are scheduled. Reminder emails will be sent 1 week prior to the group. Staff who voluntarily opt-in will be sent an information package no later than 1 week prior to the group. All participants will be required to sign a consent form.

4.2 Patient safety

Patients will not be recruited as they are not the target participants of this research (participants are nursing staff). It is plausible that patients will not want the nurse caring for them to be observed, particularly when the nurses are engaged in patient-facing activities e.g., measuring vital signs. Hence, patients will be notified verbally by the researcher and/or the member of nursing staff when the researcher is present on the ward. This information will also be displayed on laminated signs around the ward when the researcher is present and observing staff. If a patient and/or visitor indicates that they are unhappy with their nurse being observed, then the researcher will withdraw and will ensure that they do not observe participants (staff) when they are in that patient's bed area.

It is possible that the researcher will observe clinical practice that is considered unsafe and does not adhere to local policy and procedure e.g., a patient with clear signs of physiological deterioration not receiving an appropriate response. An 'escalation protocol' for the researcher to follow in this situation has been devised and agreed by appropriate hospital staff. It is also plausible that a participant will make a disclosure during an interview that pertains to overt patient harm or an issue of safeguarding. Participants will be informed - at the beginning of the interview – that in these circumstances the researcher may need to notify their line manager so that further investigation can take place. If such a disclosure is made, the

researcher will signal this within the interview and offer the participant the opportunity to be part of this conversation.

4.3 Research governance

This research protocol was independently reviewed by the local Research Ethics Committee (REC) held in the sponsor organisation (a higher education institution); and a full National Health Service REC. Favourable opinion and permissions to conduct all 3 phases of the research were granted in August 2018 (REC ref: PhD/18-19/03) and October 2018 (REC ref: 18/NS/0118) respectively. Local (hospital level) permissions from the Research and Development department were granted in November 2018 (R&D ref: 18/0569).

5. DISCUSSION

In this paper, we report a replicable method for developing a behaviour change intervention to improve responses to an elevated NEWS. Despite the level of attention that afferent limb failure (ALF) has attracted from clinicians, health service researchers and policy-makers, the problem of 'sub-optimal care' of the deteriorating ward patient persists, almost two decades after it was first described (Findlay, Shotton, & Mason, 2012; McQuillan et al., 1998; NCEPOD, 2018). Many of the existing interventions targeting ALF are educational and appear to have been developed based on a *tacit* assumption that a lack of staff 'knowledge' and 'skills' are the major barriers to afferent limb behaviour (Connell et al., 2016; Lyons et al., 2018). In a systematic review, conducted to report the effectiveness of educational interventions at improving responses to deteriorating patients, only two studies from the sample (n=23) attempted to measure directly the association between education and patient outcomes (Connell et al., 2016). One study, reported no significant difference in staff awareness of risk, 30-day patient mortality and 180-day patient mortality, following a 1-day multi-disciplinary

educational intervention (Fuhrmann, Perner, Klausen, Østergaard, & Lippert, 2009). At present, the evidence supporting educational programmes as effective interventions to change clinical staff' afferent limb behaviour remains equivocal. Additionally, there is increasing acknowledgement that when actioning behaviours of the afferent limb, staff behaviour is likely influenced by a range of different mediators (barriers and enablers) i.e., it is unlikely that a lack of knowledge and skills are the only barriers to afferent limb behaviour (Chua et al., 2017; Connell et al., 2016; Rihari-Thomas, DiGiacomo, Phillips, Newton, & Davidson, 2017).

The 14 domains of the Theoretical Domains Framework (TDF) provide broad coverage of the potential barriers and enablers to behaviour change (Atkins et al., 2017). Systematically applying the TDF, using the methods described, should advance our understanding of why ALF persists and enable the development of a theory-based intervention which is more likely to result in behaviour change and can be tested empirically in future research (Craig et al., 2008).

5.1 Limitations

The research required to develop this intervention will be undertaken in one metropolitan teaching hospital. We acknowledge that the barriers and enablers to afferent limb behaviour may vary between organisations and that following local feasibility testing, further multi-site work would be required if larger scale-up were to be considered.

Anonymised conflict of interest statement

No conflict of interest has been declared by the author(s).

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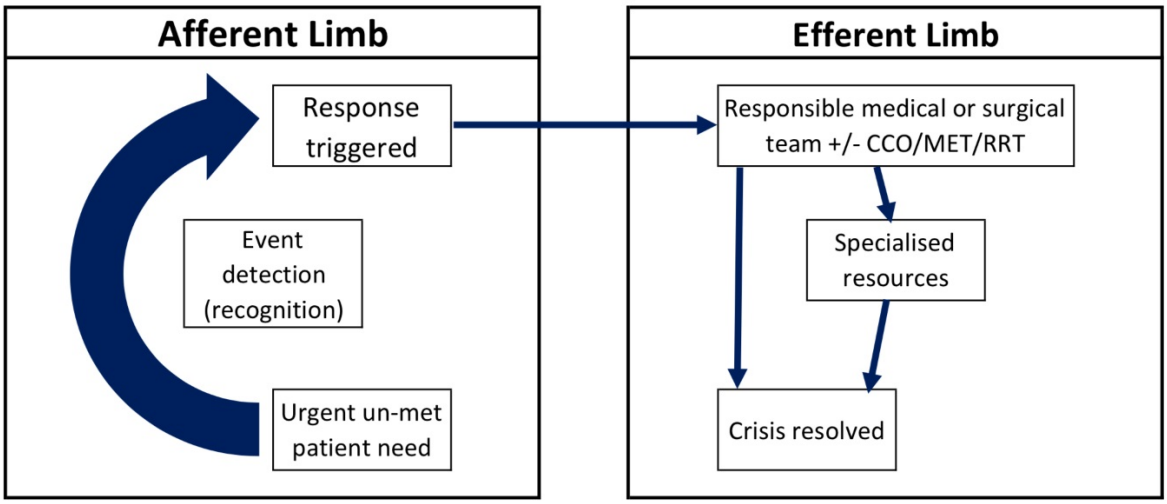

Adapted from: DeVita MA, Bellomo R, Hillman K, Kellum J, Rotondi A, Teres D, et al. (2006) Findings of the first consensus conference on medical emergency teams. *Critical Care Medicine*. 34(9):2463

Figure 1 – Conceptual model of the Rapid Response System (RRS)

TDF (v2) domain*	Content of the domain and *Plain-English explanation*†
1. Knowledge	An awareness of the existence of something *What do they know and how does that influence what they do?*
2. Skills	An ability or proficiency acquired through practice
3. Social/Professional role and identity	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting *How does who they are as a Health Care Provider influence whether they do something or not?*
4. Beliefs about Capabilities	Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use *Do they think they can do what they should do and how does that influence whether they do it or not?*
5. Optimism	The confidence that things will happen for the best or that desired goals will be attained *The confidence that things will happen for the best or that desired goals will be attained*
6. Beliefs about Consequences	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
7. Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus *How have their experiences (good and bad) of doing it in the past influence whether or not they do it?*
8. Intentions	A conscious decision to perform a behaviour or a resolve to act in a certain way *How does how inclined they are to do something influence whether they will do it?*
9. Goals	Mental representations of outcomes or end states that an individual wants to achieve *How important is what they do and does that influence whether or not they do it? What standards are they trying to reach, how does that influence whether or not they do it?*
10. Memory, Attention and Decision Processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
11. Environment, Context and Resources	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour *What are the things in their environment that influence what they do and how do they influence?*
12. Social Influences	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviour *What do others think of what they do? Who are they and how does that influence what they do?*
13. Emotion	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event

	How do they feel about what they do and do those feelings influence what they do?
14. Behavioural Regulation	Anything aimed at managing or changing objectively observed or measured actions *Do they have strategies that have/do enable them to enact the behaviour?*

Adapted from:

*Atkins, L., Francis, J., Islam, R., O'Connor, D., Patey, A., Ivers, N., … Michie, S. (2017). A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science*, *12*(1), 77

†Additional file 3 from: Presseau, J., Mutsaers, B., Al-Jaishi, A. A., Squires, J., McIntyre, C. W., Garg, X., … Grimshaw, J.M. (2017). Barriers and facilitators to healthcare professional behaviour change in clinical trials using the Theoretical Domains Framework: a case study of a trial of individualized temperature-reduced haemodialysis. *Trials*, *18*(1), 227. https://doi.org/10.1186/s13063-017-1965-9

Figure 2 – Domains and content of the Theoretical Domains Framework (TDFv2)

Example BCTs	Description
Goal Setting	Set or agree on a goal defined in terms of the behaviour to be achieved.
Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of the behaviour change strategy.
Social Support (unspecified)	Advise on, arrange or provide social support (e.g., from friends, relatives, colleagues, buddies or staff) or non-contingent praise or reward for performance of the behaviour.
Instruction on how to perform a behaviour	Advise or agree how to perform the behaviour.
Salience of consequences	Use methods specifically designed to emphasise the consequences of performing the behaviour with the aim of making them more memorable.
Social comparison	Draw attention to others' performance to allow comparison with the person's own performance.
Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.
Habit reversal	Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour.
Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour.
Social reward	Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behaviour.
Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate performance of the behaviour.
Re-structuring the physical environment	Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments).
Identification of self as role model	Inform that one's own behaviour may be an example to others.
Self-talk	Prompt positive self-talk (aloud or silently) before and during the behaviour.
Imaginary reward	Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence.

Taken from: Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., … Wood, C. E. (2013). The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine*, *46*(1), 81–95.

Figure 3 – Fifteen example Behaviour Change Techniques (BCTs) with descriptions

Supplementary file 1

Nominal group ranking document

Please use the table below to rank the behaviour change techniques and modes of delivery that have been discussed during this nominal group meeting.

1. How well accepted would the techniques be by clinical staff?

In the table below, rank the behaviour change techniques and modes of delivery according to how well accepted you think that they would be by clinical staff in your Trust.

Rank	Behaviour change technique (BCT)	Mode of delivery (how the BCT could be delivered in your Trust)
1 Most accepted		
2		
3		
4		
5 Least accepted		

2. How easily could the techniques be put into practice within your Trust?

In the table below, rank the behaviour change techniques and modes of delivery according to how easily you think they could be put into practice within your Trust.

Rank	Behaviour change technique (BCT)	Mode of delivery (how the BCT could be delivered in your Trust)
1 Easiest		
2		
3		
4		
5 Least easy		

Supplementary file 2

Overview of approaches for staff members to opt-out of phase 1:

At every meeting or briefing prior to phase 1 data collection, the researcher will reiterate that staff should report if they do not wish to be observed or approached during the period of observation. Staff who do not wish to be observed/approached will be asked prospectively to sign an opt-out form. Copies of these forms (in addition to participant information sheets) will be made available at every meeting between the researcher and staff. Copies will also be left in the staff room along with a sealed box so that staff can privately complete and return the opt-out form. The completed opt-out form will allow the researcher to identify staff on duty who have chosen to opt out (by cross-checking with the staff duty-rota), so that no further information can be collected from these individuals. Details of these staff will not be shared with colleagues or managers. At the beginning of a period of observation (i.e., at the start of a clinical shift), staff on duty will be given a further opportunity to opt-out if they do not wish to be observed or approached. All staff will be reminded that they can opt-out at any stage and will not be required to justify or rationalise this decision. It is plausible that some staff members will not opt-out prospectively, but instead choose to opt-out midway through the observational phase of data collection. In these circumstances, no further data will be collected from these staff however, any data that pre-dates their decision to opt-out will not be identifiable. As such, it will not be possible to destroy field data already collected prior to the participant deciding to opt-out (this is emphasised within participant information materials).

Opt-out form

Please initial box

1.	I confirm that I have had the project explained to me, and I have read the participant information sheet (v2.6 29/10/18), which I may keep for my records. I have decided that I do not wish to participate in the study and therefore I withdraw consent to be observed directly or approached by the researcher. I understand that the researcher may be present observing and/or interacting with other staff when I am working.	
2.	This information will be held by City as data controller and processed for the following purpose(s): • At the beginning of a period of data collection (observation), the researcher will cross check this data with staff allocation information to identify who has opted out of the study and does not wish to be observed • The details of staff who have chosen not to participate will not be disclosed to any other individual *The lawful basis for processing under General Data Protection Regulation (GDPR) for personal data is public task* ***GDPR Article 6(1)(e)***	
3.	I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation. City, University of London will retain this information for a period of 10 years. At this time this information will be destroyed.	

4.	I agree to City recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in this statement and my consent is conditional on City complying with its duties and obligations under the under the General Data Protection Regulation (GDPR).	
5.	I would like to opt-out of this study.	

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of Researcher	Signature	Date

When completed, 1 copy for participant; 1 copy for researcher file.